REMARKS

Claim Status

Claims 1, 6, 8, 9, 23, 25-27 and 29-38 are pending in the present application.

Claims 2-5, 7, 10-22, 24 and 28 were previously canceled. No additional claims fee is believed to be due.

Rejection Under 35 USC §103(a) Over Bailly et al. (6,030,953) in view of Park et al. (5,750,585)

Claims 1, 6, 8, and 9 have been rejected under 35 USC §103(a) as being unpatentable over Bailly et al. (6,030,953) (hereinafter "Bailly") in view of Park et al. (5,750,585) (hereinafter "Park"). The Office Action states that Bailly teaches a composition comprising chitosan (a HIPE foam) in combination with an inhibitor of gastrointestinal lipase (a lipase inhibitor). The Office Action concedes that Bailly does not teach the HIPE foam having a density of less than about 0.1 g/cc. However, the Office Action states that Park teaches a non-digestible, non-absorbable, open-celled HIPE foam composition and method of orally administering said forms for treatment of obesity. The Office Action states that the HIPE foams composition in Park ranges from 0.0015 to about 0.7 g/cc and more preferably from 0.015 to 0.5 g/cc. Applicants respectfully traverse this rejection based on the remarks contained herein.

In order for a case of obviousness to be established, three criteria must be met. First, there must be some apparent reason, i.e., some teaching, suggestion, or motivation, to modify reference teachings (USPTO Examination Guidelines for Determining Obviousness in View of *KSR Int'l. Co., v. Teleflex, Inc.*, No. 04-1350 (US, Apr. 30, 2007)). Second, there must be a reasonable expectation of success. Finally, the prior art references, when combined, must teach or suggest all the claim limitations (MPEP 2143).

Independent claim 1 recites a composition suitable for oral administration to an animal for the purpose of sequestering one or more lipophilic materials present in the gastrointestinal tract of the animal, wherein the composition comprises a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; wherein said polymeric foam is a HIPE foam having a density of less than about 0.1 g/cc; wherein said polymeric material is selected from the group consisting of celluloses, chitins, chitosans, natural sponges, synthetic sponges, polyvinyl acetate, polyvinyl alcohol,

polyurethanes, polyacrylates, polymethacrylates, polystyrenics, polyolefins, copolymers thereof, and mixtures thereof; and wherein said composition is in a form selected from the group consisting of capsule, pill, caplet, tablet, chewable tablet, suspension, suppository, and combinations thereof. The current application teaches that a high internal phase emulsion foam are prepared by polymerization of the oil phase of certain water-in-oil emulsions having a relatively high ratio of water phase to oil phase, commonly known in the art as "HIPE." See Applicants' specification page 11, lines 25-27. Therefore, a polymeric foam material which results from the polymerization of such emulsions is referred to herein as a "HIPE foam." See Applicants' specification page 11, lines 27-28. HIPE foams comprise a generally lipophilic or amphiphilic, flexible or semi-flexible, nonionic polymeric foam structure of interconnected open-cells. See Applicants' specification page 11, lines 28-30. Therefore the current application is not claiming the entire genus of polymeric material but calls out specific polymeric material that is present in the foam that is claimed and described in the current specification that must be nondigestible, non-absorbable, open-celled polymeric foam and a high internal phase emulsion foam.

For the reasons that follow, Applicants submit that, even when combined, Bailly and Park fail to teach or suggest all of the claim limitations of independent claims 1. Bailly discloses an inhibitor of gastrointestinal lipase and at least one compound selected from the group consisting of chitosan, its derivatives and salts thereof. See Column 1, lines 43-47. Bailly discloses that chitosan is superior over microcrystalline cellulose in reducing anal leakage of oil. See Column 3, lines 20-23. Bailly does not teach or suggest, *inter alia*, a HIPE foam having a density of less than about 0.1 g/cc.

The Park reference discloses hydrogels which are described at column 3 to column 4, starting at line 50 of column 3. The hydrogels of Park are prepared by introducing a gas into a monomer solution comprising at least one *hydrophilic* olefin monomer compound. The hydrogels of Park are not disclosed as HIPE foams and are not formed from an emulsification process using hydrophobic monomers. The compositions of Park are formed by introducing gas into a hydrophilic olefin monomer solution during polymerization of the monomer. Thus, the compositions of Park and the present invention are not the same because the compositions of Park are not HIPE foams. Additionally, the only mention of treatment of gastric conditions by Park is as a physical

barrier due to the large swelled size of the hydrogels of Park such that the large swelled hydrogel reduces the amount of physical space in the stomach. There is nothing in Park that teaches or suggests that the hydrogels would sequester one or more lipophilic materials. Park does not teach or suggest, *inter alia*, a HIPE foam having a density of less than about 0.1 g/cc.

Furthermore, based on the disclosure in Bailly and Park the Office Action has not provided the motivation why one with normal skill in the art would create a composition suitable for oral administration to an animal for the purpose of sequestering one or more lipophilic materials present in the gastrointestinal tract of the animal, wherein the composition comprises a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; wherein said polymeric foam is a HIPE foam having a density of less than about 0.1 g/cc. "The citing reference that merely indicate[s] that isolated elements and/or features recited in the claims are known is not sufficient basis for concluding that the combination of claimed elements would be obvious." See Ex parte Hiyamizu, 10 U.S.P.Q. 2D (BNA) 1393, 1394 (1988). There should be something in the prior art or a convincing line of reasoning in the answer suggesting the desirability of combining the reference in such a manner as to arrive at the claimed invention. Note In re Dembiczak 175 F. 3d 994, 999 (Fed. Cir. 1999). "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be **important** to identify **a reason** that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way claimed new invention does. This is so because **inventions in most, if not all, instances rely upon building blocks since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.**" KSR, 1727 S. Ct. 1727, at 1741 (2007) (emphasis added). A quote acknowledging a "helpful insight" by the Court of Customs and Patent Appeals when that court first established TSM. "Often, it will be necessary for a court to look to interrelated teachings of multiple patents; . . . **to determine whether there was an apparent reason** to combine the known elements in the fashion claimed by the patent at issue." KSR, 1727 S. Ct. at 1740-41 (emphasis added).

There is no identified **reason** that would have prompted a person of ordinary skill in the relevant field to combine the elements of Bailly and Park to result in the currently claimed invention. The Office Action has not provided this apparent reason nor do the references alone or in combination provide this motivation to combine. Additionally, the references alone or in combination do not provide the teaching or suggestion for a composition suitable for oral administration to an animal for the purpose of sequestering one or more lipophilic materials present in the gastrointestinal tract of the animal, wherein the composition comprises a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; wherein said polymeric foam is a HIPE foam having a density of less than about 0.1 g/cc.

Even assuming *arguendo* that one were to combine Bailly and Park one would still fall short of the Applicants' claimed invention only to arrive at an inhibitor of gastrointestinal lipase with chitosan and a hydrogel.

Accordingly, Claims 1, 6, 8, and 9 are nonobvious over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

Rejection Under 35 USC §103(a) Over Daggy et al. (6,607,749 B1)
in view of Park et al. (5,750,585)

Claims 1, 6, 8, and 9 have been rejected under 35 USC §103(a) as being unpatentable over Daggy et al. (6,607,749 B1) (hereinafter "Daggy") in view of Park. The Office Action states that Daggy teaches a composition comprising methylcellulose (a HIPE foam) in combination with a lipstatin inhibitor (a lipase inhibitor). The Office Action concedes that Daggy does not teach the HIPE foam having a density of less than about 0.1 g/cc. However, the Office Action states that Park teaches a non-digestible, non-absorbable, open-celled HIPE foam composition and method of orally administering said forms for treatment of obesity. The Office Action states that the HIPE foams composition in Park ranges from 0.0015 to about 0.7 g/cc and more preferably from 0.015 to 0.5 g/cc. Applicants respectfully traverse this rejection based on the remarks contained herein.

Independent claim 1 recites a composition suitable for oral administration to an animal for the purpose of sequestering one or more lipophilic materials present in the gastrointestinal tract of the animal, wherein the composition comprises a non-digestible,

non-absorbable, open-celled polymeric foam comprising a polymeric material; wherein said polymeric foam is a HIPE foam having a density of less than about 0.1 g/cc; wherein said polymeric material is selected from the group consisting of celluloses, chitins, chitosans, natural sponges, synthetic sponges, polyvinyl acetate, polyvinyl alcohol, polyurethanes, polyacrylates, polymethacrylates, polystyrenics, polyolefins, copolymers thereof, and mixtures thereof; and wherein said composition is in a form selected from the group consisting of capsule, pill, caplet, tablet, chewable tablet, suspension, suppository, and combinations thereof.

For the reasons that follow, Applicants submit that, even when combined, Daggy and Park fail to teach or suggest all of the claim limitations of independent claims 1. Daggy et al. discloses a swallowable solid dosage form of a combination product which contains a bulking soluble fiber, preferably methylcellulose, which is convenient to take and transport, is preferably sugar free, and a lipstatin derivative, preferably orlistat. See Column 2, lines 55-59. Daggy et al. does not teach or suggest a HIPE foam having a density of less than about 0.1 g/cc.

Applicants assert that the arguments presented above regarding Park in traversing the previous § 103(a) rejection also applies to the present rejection. Park does not teach or suggest, *inter alia*, a HIPE foam having a density of less than about 0.1 g/cc.

There is no identified **reason** that would have prompted a person of ordinary skill in the relevant field to combine the elements of Daggy and Park to result in the currently claimed invention. The Office Action has not provided this apparent reason nor do the references alone or in combination provide this motivation to combine. Additionally, the references alone or in combination do not provide the teaching or suggestion for a composition suitable for oral administration to an animal for the purpose of sequestering one or more lipophilic materials present in the gastrointestinal tract of the animal, wherein the composition comprises a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; wherein said polymeric foam is a HIPE foam having a density of less than about 0.1 g/cc

Even assuming *arguendo* that one were to combine Daggy and Park one would still fall short of the Applicants' claimed invention only to arrive at an inhibitor of gastrointestinal lipase with methylcellulose and a hydrogel.

Accordingly, Claims 1, 6, 8, and 9 are nonobvious over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

Rejection Under 35 USC §103(a) Over Bailly et al. (6,030,953) or Daggy et al. (6,607,749 B1) in View of Park et al. (5,750,585) and Further in View of Niazi (6,251,421)

Claims 23 and 25-27 have been rejected under 35 USC §103(a) as being unpatentable over Bailly or Daggy in view of Park and further in view of Niazi (6,521,421). The Office Action applies Bailly, Daggy, and Park as before. The Office Action states that Niazi states that compositions can be in the form of commercial packs containing a lipase inhibitor and instructions for its uses in the treatment of obesity or hyperlipidemia. Applicants respectfully traverse this rejection based on the remarks contained herein.

Independent claim 23 recites a kit comprising: (a) a first composition suitable for oral administration comprising a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; wherein said polymeric foam is a HIPE foam having a density of less than about 0.1 g/cc; wherein said polymeric material is selected from the group consisting of celluloses, chitins, chitosans, natural sponges, synthetic sponges, polyvinyl acetate, polyvinyl alcohol, polyurethanes, polyacrylates, polymethacrylates, polystyrenics, polyolefins, copolymers thereof, and mixtures thereof; and wherein said first composition is in a form selected from the group consisting of capsule, pill, caplet, tablet, chewable tablet, suspension, suppository, and combinations thereof; and (b) a second composition comprising a lipase. Independent claim 27 recites a kit comprising: (a) a composition suitable for oral administration comprising a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; wherein said polymeric foam is a HIPE foam having a density of less than about 0.1 g/cc; wherein said polymeric material is selected from the group consisting of celluloses, chitins, chitosans, natural sponges, synthetic sponges, polyvinyl acetate, polyvinyl alcohol, polyurethanes, polyacrylates, polymethacrylates, polystyrenics, polyolefins, copolymers thereof, and mixtures thereof; and wherein said composition is in a form selected from the group consisting of capsule, pill, caplet, tablet, chewable tablet, suspension, suppository, and combinations thereof; and (b) information associated with

the composition that use of the composition will provide one or more benefits selected from the group consisting of sequestration of lipophlic materials, treatment of gastrointestinal distress, treatment of fecal urgency, treatment of obesity, weight loss, weight control, treatment of hyperlipidemia, treatment of diarrhea, inhibition of anal leakage, reduction of levels of toxic substances, treatment of Type II Diabetes, delay of onset of Type II Diabetes, and combinations thereof.

Applicants assert that the arguments presented above regarding Bailly, Daggy, and Park in traversing the previous § 103(a) rejections also applies to the present rejection. The references do not teach or suggest a composition that comprises, *inter alia*, a HIPE foam having a density of less than about 0.1 g/cc.

Niazi discloses pharmaceutical compositions containing an effective amount of an inhibitor of gastrointestinal lipase, and an effective amount of at least one compound selected from the group consisting of psyllium fiber or husk, its derivatives and salts thereof. See Column 1, lines 54-59. Niazi does not teach or suggest combining enzyme inhibitors with foam.

Therefore, there is no teaching or suggestion in Bailly or Daggy, Park and Niazi for a kit comprising a composition suitable for oral administration comprising a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; wherein said polymeric foam is a HIPE foam having a density of less than about 0.1 g/cc. Because there is no teaching or suggestion at all, in any of the cited documents, of a HIPE foam having a density of less than about 0.1 g/cc, there can be no expectation of success.

Even assuming *arguendo* that one were to combine Bailly or Daggy, Park and Niazi one would still fall short of the Applicants' claimed invention only to arrive at an inhibitor of gastrointestinal lipase with chitosan or methylcellulose, a hydrogel, and psyllium fiber or husk.

Accordingly, Claims 23 and 25-27 are nonobvious over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

Rejection Under 35 USC §103(a) Over Bailly et al. (6,030,953) or Daggy et al. (6,607,749 B1) in View of Park et al. (5,750,585) in View of Shiveley et al. (5,817,704) and Further in View of Niazi (6,251,421)

Claims 29-38 have been rejected under 35 USC §103(a) as being unpatentable over Bailly or Daggy in view of Park in view of Shiveley et al (5,817,704) (hereinafter "Shiveley") and further in view of Niazi. The Office Action applies Bailly, Daggy, Park, and Niazi as before. The Office Action concedes that the instant invention differs from the cited references in that the cited references do not teach the glass transition temperature from about -40 °C to 90 °C to form said oral dosage forms. The Office Action states that Shiveley states that foams intended for applications requiring flexibility should contain at least in continuous region having a Tg as low as possible is well-known in the art. Applicants respectfully traverse this rejection based on the remarks contained herein.

Independent claim 29 recites a composition suitable for oral administration to an animal for the purpose of sequestering one or more lipophilic materials present in the gastrointestinal tract of the animal, wherein the composition comprises a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; wherein said polymeric foam is a HIPE foam having: (a) a specific surface area per foam volume of at least about 0.01 m^2/cc; and (b) a glass transition temperature (Tg) from about -40°C to about 90°C; wherein said polymeric material is selected from the group consisting of celluloses, chitins, chitosans, natural sponges, synthetic sponges, polyvinyl acetate, polyvinyl alcohol, polyurethanes, polyacrylates, polymethacrylates, polystyrenics, polyolefins, copolymers thereof, and mixtures thereof; and wherein said composition is in a form selected from the group consisting of capsule, pill, caplet, tablet, chewable tablet, suspension, suppository, and combinations thereof. Independent claim 33 recites a kit comprising: (a) a first composition suitable for oral administration comprising a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; wherein said polymeric foam is a HIPE foam having: (i) a specific surface area per foam volume of at least about 0.01 m^2/cc; and (ii) a glass transition temperature (Tg) from about -40°C to about 90°C; wherein said polymeric material is selected from the group consisting of celluloses, chitins, chitosans, natural sponges, synthetic sponges, polyvinyl

acetate, polyvinyl alcohol, polyurethanes, polyacrylates, polymethacrylates, polystyrenics, polyolefins, copolymers thereof, and mixtures thereof; and wherein said first composition is in a form selected from the group consisting of capsule, pill, caplet, tablet, chewable tablet, suspension, suppository, and combinations thereof; and (b) a second composition comprising a lipase inhibitor. And independent claim 36 recites a kit comprising: (a) a composition suitable for oral administration comprising a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; wherein said polymeric foam is a HIPE foam having: (i) a specific surface area per foam volume of at least about 0.01 m^2/cc; and (ii) a glass transition temperature (Tg) from about -40°C to about 90°C; wherein said polymeric material is selected from the group consisting of celluloses, chitins, chitosans, natural sponges, synthetic sponges, polyvinyl acetate, polyvinyl alcohol, polyurethanes, polyacrylates, polymethacrylates, polystyrenics, polyolefins, copolymers thereof, and mixtures thereof; and wherein said composition is in a form selected from the group consisting of capsule, pill, caplet, tablet, chewable tablet, suspension, suppository, and combinations thereof; and (b) information associated with the composition that use of the composition will provide one or more benefits selected from the group consisting of sequestration of lipophlic materials, treatment of gastrointestinal distress, treatment of fecal urgency, treatment of obesity, weight loss, weight control, treatment of hyperlipidemia, treatment of diarrhea, inhibition of anal leakage, reduction of levels of toxic substances, treatment of Type II Diabetes, delay of onset of Type II Diabetes, and combinations thereof.

Applicants assert that the arguments presented above regarding Bailly, Daggy, Park, and Niazi in traversing the previous § 103(a) rejections also applies to the present rejection. The references do not teach or suggest a composition that comprises, *inter alia*, a HIPE foam having a specific surface area per foam volume of at least about 0.01 m^2/cc.

Shiveley discloses a HIPE-derived heterogeneous polymeric foam structure of interconnected open cells, wherein the foam structure has at least two distinct regions. See Column 3, lines 32-35. Shiveley discloses that the heterogeneous polymeric foams are useful in applications involving energy dissipation, thermal insulation, filtration, and absorbent cores in absorbent articles. See Column 23, lines 66-67 and Column 25, lines 1-6. Specifically, Shively discloses that the foams can be employed in sorbents for environmental waste oil, bandages or dressings, dust mop heads, wet mop heads, fluid

dispensers, packaging, shoes, sorbents for odor and/or moisture, cushions, gloves, and other uses. See Column 24 lines 66-67 and Column 25, lines 1-27. The current invention claims, *inter alia*, a composition suitable for oral administration to an animal for the purpose of sequestering one or more lipophilic materials present in the gastrointestinal tract of the animal. Shiveley et al. does not teach or suggest compositions suitable for oral administration.

Therefore, there is no teaching or suggestion in Bailly or Daggy, Park, Shiveley, and Niazi for a composition suitable for oral administration to an animal for the purpose of sequestering one or more lipophilic materials present in the gastrointestinal tract of the animal, wherein the composition comprises a non-digestible, non-absorbable, open-celled polymeric foam comprising a polymeric material; wherein said polymeric foam is a HIPE foam having a specific surface area per foam volume of at least about 0.01 m^2/cc; and a glass transition temperature (Tg) from about -40°C to about 90°C.

Even assuming *arguendo* that one were to combine Bailly or Daggy, Park, Shiveley, and Niazi one would still fall short of the Applicants' claimed invention only to arrive at an inhibitor of gastrointestinal lipase with chitosan or methylcellulose, a hydrogel, psyllium fiber or husk, and a heterogeneous polymeric foam useful in applications involving energy dissipation, thermal insulation, filtration, and absorbent cores in absorbent articles.

Accordingly, Claims 29-38 are nonobvious over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

CONCLUSION

This Response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied references. Reconsideration of this application and allowance of the pending claims are respectfully requested.

Respectfully submitted,
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